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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,162	03/08/2001	Robert Getts	4081.005	6213

7590 09/30/2004

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/802,162

Applicant(s)

GETTS, ROBERT

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Acknowledgement is made for the request to establish continued prosecution application (RCE) filed on September 7, 2004. The request for RCE is accepted and is established with the status of the application as follows:
 - a. the filling date of this RCE is established as March 8, 2001;
 - b. claims 1-26 are pending.
2. Applicants' response to the earlier office action filed along with RCE, on September 7, 2004 is has been entered.

Response to arguments

3. Applicants' response to the office action is fully considered and found persuasive in part.
4. With regard to the rejections made in the previous office actions under provisional double-patenting with the co-pending applications 09/ 908,950, 10/050,088, and 10/234, 069, Applicants' arguments are fully considered and the rejections. The instant claims encompass the limitations of the claims in these co-pending applications and therefore the rejections are maintained herein until a terminal disclaimer is submitted.
5. With regard to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive, and the rejection is withdrawn herein in view of the arguments and new grounds of rejections.

New Grounds of Rejections

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dellinger et al. (USPN. 5,853,993) in view of Nilsen (USPN. 6,274,723).

Dellinger et al. teach a method claim 1-2 and 18, for detecting nucleic acids on a solid support, wherein the method comprises

1) (a) taking an immobilized capture probe (see column 4, lines 50-67, column 3, lines 44-50);

(b) taking a first component comprising cDNA reagents (target analyte comprising mRNA having a capture sequence (homopolymeric tailing or Poly A or poly U tail) (see column 3, lines 20-24, column 5, lines 4-14);

(c) taking a second component (reporter probe) comprising having at least on first arm comprising label and at least one second arm having a second nucleotide sequence which is complementary to the homopolymeric region on the target analyte (see column 5, lines 23-32, column 10, lines 21-49), wherein said second sequence binds with the capture sequence (homopolymeric region) of the target analyte forming reporter-analyte hybrid (see column 1, lines 53-61);

2) mixing said first and second components at a temperature and for a time sufficient to enable said first component to bind with the second component (see column 1, lines 53-61, column 10, lines 51-57);

3) incubating this mixture with said immobilized capture probe to enable the first nucleotide sequence to bind to said first component, generating a hybridization pattern (see column 1, lines 61-63, column 10, lines 55-60);

with regard to claim 7-8, Dellinger et al. teach that the time sufficient to enable the second and first component is 1 hour to 3 hours (see column 10, lines 52-55);

with regard to claim 10, Dellinger et al. disclose that the detection of the hybridization signal by scanning the microarray using fluoroimager instrument (see column 10, lines 61-62);

With regard to claim 3-4, 11-17, 24-26, Dellinger et al. also disclose washing the microarray to purge unattached reporter probes after hybridization reaction (see column 10, lines 58-60, column 9, lines 30-34);

With regard to claim 5-6, 9, 13, Dellinger et al. teach that the method comprises hybridization buffer (see column 10, lines 51-55);

With regard to claims 20-21, the mixing of first and second components is conducted on the said microarray or in solution (off microarray) (see column 4, lines 50-66).

However, Dellinger et al. did not teach use of dendrimer nucleotide sequences.

Nilsen et al. teach a method of claims 1-26, for detecting a specific nucleic acid in a target sample using a dendrimeric probe wherein Nilsen et al. teach that the method comprises (i) contacting a bead having specific probe sequences with a mixture containing a first component comprising labeled target nucleic acid (DNA or RNA) having a capture sequence and a second component comprising a dendrimer having at least one arm with a nucleotide sequence complementary to the capture sequence of the first component (see column 14, lines 30-35, column 15, lines 37-63); (ii) mixing the first and second components at a temperature to form a

bridge between the two components to enable the cross-linking of first component to the second (see column 16, lines 8-11); and incubating the bound mixture with the said bead and detecting signal as an indication of the binding of the target sequence to the specific probe sequence on the bead (see column 16, lines 12-67, column 18, lines 27-51). Nilsen et al. also teach that the method comprises annealing times ranging from 8 minutes (see column 20, lines 24-44) to overnight to 2-6 weeks (see column 3, lines 49-60); detection of hybridization pattern includes detecting the detectable signal (see column 20, lines 38-40); the method comprises hybridization buffer (see column 19, lines 14-26); the unbound dendrimers were removed by a washing step (see column 20, lines 35-37); and the isolation of nucleic acid includes spin column (see column 20, lines 17-19).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method for using microarray hybridization as taught by Dellinger et al. with a method for detecting a nucleic acid sequence using dendrimer as taught by Nilsen et al. to achieve expected advantage of developing an enhanced sensitivity of detecting a target nucleic acid because Nilsen et al. states that "background noise could be generated in conventional assay not only from binding to a solid support, but also from binding of the probe to nonhomologous DNA sequences. An open branching of a dendrimeric DNA have many degrees of freedom in their movement relative to each other and have a high avidity for DNA that is complementary to the non-annealed single stranded sequences (see column 18, lines 14-26, column 7, lines 14-19). An ordinary practitioner would have been motivated to combine the method of Dellinger et al. with the step of adding dendrimeric probe as taught by Nilsen et al. in order to achieve the expected advantage of developing a sensitive method for

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detecting a target nucleic acid because the addition of the limitation as taught by Nilsen et al. would reduce non-specific binding and reduce background noise and enhance specific hybridization signal.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
September 21, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER

9/24/04